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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/766,863	01/19/2001	Thomas J. Powell	15966-641 CURA-141)	9092

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09/12/2002

Ivor R. Elrifi
Mintz, Levin, Cohn, Ferris,
Glovsky and Popeo, P.C.
One Financial Center
Boston, MA 02111

EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 09/12/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/766,863

Applicant(s)

POWELL ET AL.

Examiner

Suryaprabha Chunduru

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' response to the office action and amendment (Paper No. 9) filed on April 22, 2002 has been entered.

Response to Arguments

2. Applicant's response to the office action (Paper No.9) is fully considered and deemed persuasive.

3. With respect to the rejection made in the previous office action under 35 U.S.C. 102(b), Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

4. With respect to the rejection made in the previous office action under 35 U.S.C. 103(a), Applicants' arguments have been considered but are moot in view of the new ground(s) of rejection.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-17 and 19 are rejected under 35 U.S.C. 102(a) as being anticipated by Johnson et al. (WO 99/37817).

With reference to the instant claims 1, and 11 and 19, Johnson et al. teach a method of identifying the function of a test compound, wherein Johnson et al. disclose that the method comprises (i) providing a plurality of cells, the plurality comprising at least two different cell

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types and exposing the plurality of cells with a test compound (see page 53, lines 1-60; (ii) measuring expression of one or more genes in the said cell types and comparing the expression of said genes with a reference cell and an alteration in said gene expression indicates the function of said test compounds (see page 53, claim 1, lines 7-15, page 11, lines 3-5).

Johnson et al. also teach that the method comprises

With reference to the instant claims 2-9, expression of at least two genes in two different cell types (see page 53, claims 2 and 3) Johnson et al. further defines different gene-cell combination as the same gene in two or more host cell types or, two or more different genes in the same host cell type (see page 7, lines 24-31), which indicates more than two cell types and more than two genes are permissive in the said method which is supported by the results in table 1 of Johnson et al. disclosure (see page 20, table 1, lines 1-4);

With reference to the instant claims 10, and 17, cells are provided in container (plates) and the cell types consist of HepG2 cells (see page 27, lines 1-11);

With reference to the instant claim 12, gene expression greater than or equal to 3-fold was taken as an indication of modulated gene expression by a test compound. (see page 28, lines 19-20);

With reference to the instant claim 13, test compound could be a polypeptide (see page 54, claim 14);

With reference to the instant claim 14, plurality of cell types were contacted with two or more test compounds (see page 54, claim 12);

With reference to the instant claims 15-16, plurality of cells include mammalian cells from human subjects (see page 39, lines 12-19).

Thus, the disclosure of Johnson et al. meets the limitations in the instant claims.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (WO 99/37817) and in view of MacLeod et al. (USPN. 6,221,600).

Johnson et al. teach a method of identifying the function of a test compound, wherein Johnson et al. disclose that the method comprises (i) providing a plurality of cells, the plurality comprising at least two different cell types and exposing the plurality of cells with a test compound (see page 53, lines 1-60; (ii) measuring expression of one or more genes in the said cell types and comparing the expression of said genes with a reference cell and an alteration in said gene expression indicates the function of said test compounds (see page 53, claim 1, lines 7-15, page 11, lines 3-5). Johnson et al. also teach that the method comprises expression of at least

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two genes in two different cell types (see page 53, claims 2 and 3). Johnson et al. further defines different gene-cell combination as the same gene in two or more host cell types or, two or more different genes in the same host cell type (see page 7, lines 24-31), which indicates more than two cell types and more than two genes are permissive in the said method which is supported by the results in table 1 of Johnson et al. disclosure (see page 20, table 1, lines 1-4). Though Johnson et al. teach measuring gene expression by using fluorescent labels, however, Johnson et al. did not teach measuring gene expression by real-time polymerase chain reaction.

MacLeod et al. teach a method for combinatorial gene expression to identify differentially expressed genes wherein MacLeod et al. disclose that method allows multiple samples to be analyzed simultaneously (see column 4, lines 54-67, and column 5, lines 1-3) and real time polymerase chain reaction could be used to measure the gene expression (see column 6, lines 59-64).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the method of drug target screening as taught by Johnson et al. with the method of MacLeod et al. which is applicable to measure gene expression by real-time polymerase chain reaction because Johnson et al. states that 'techniques as standard northern or slot blot hybridization, nuclease protection, or quantitative PCR are limited in the number of different RNAs that can be simultaneously analyzed as well as in their amenability to automation' (see page 13, lines 27-31). One of the alternative forms to analyze more number of genes simultaneously, expressly motivated by MacLeod et al. is the use real-time polymerase chain reaction "to provide a method for the rapid quantitative analysis of multiple transcripts." An ordinary practitioner would have been motivated to combine the method of Johnson et al.

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with the method of MacLeod et al. in order to achieve the expected advantage of a sensitive and cost-effective method for screening a test compound based on real-time PCR for gene expression analysis.


Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Suryaprabha Chunduru
September 6, 2002


JEFFREY FREDMAN
PRIMARY EXAMINER